27		Honorable Cormac J. Carney				
26	Defendants.) Place: Courtroom 9B				
24 25	MASIMO CORPORATION, and DOES 1 to 100, inclusive,	Date: March 31, 2014 Time: 1:30 p.m.				
23 24	V.	AND DISMISS ACTION				
22 2 <i>3</i>	ŕ	ARBITRATION AWARD				
	Plaintiffs,	SUPPORT OF ITS MOTION TO VACATE FINAL				
20 21	MICHAEL RUHE and VICENTE CATALA,	MASIMO'S BRIEF IN				
19 20	MICHAEL DITHE and VICENTE) Civil Action No.) SACV 11-00734 CJC (MLGx)				
18	SOUTHERN DIVISION					
17	FOR THE CENTRAL DISTRICT OF CALIFORNIA					
16 17	IN THE UNITED STATES DISTRICT COURT					
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I. INTRODUCTION

The Arbitrator, Justice Richard Neal (Ret.), was supposed to decide whether Masimo created an intolerable working condition and retaliated against two salesmen who quit and sued Masimo. Instead, he used this employment dispute to issue a Final Award in which he substituted his own judgment for international testing standards about how to determine the accuracy of Masimo's medical devices.

Masimo and the FDA discussed and agreed that Masimo should follow the scientific methods established by International Organization Standardization (ISO) to determine an accuracy specification for its devices. Yet, without support from any scientific or regulatory expert or doctor, the Arbitrator pronounced his own "critical test." Based on this proposed test, he concluded that Masimo's devices are inaccurate, defective, and could endanger patients. The Arbitrator even justified punitive damages because Masimo tested the devices in a controlled setting per ISO. But Masimo did not, and could not, have agreed to arbitrate what testing methodology it should have followed. Masimo followed the testing discussed with the FDA, and the FDA did not require anything further. This question, not within the Arbitrator's authority, was also preempted by Federal Law. Therefore, the Arbitrator exceeded his power.

The Arbitrator also manifestly disregarded the law by rejecting this Court's October 2, 2013 summary judgment ruling in the parties' prior *Qui Tam* case. In that ruling, this Court rejected Plaintiffs' argument that Masimo "knowingly" promoted devices that did not meet their FDA-cleared accuracy specification. Because Plaintiffs' wrongful constructive termination theory in the Arbitration rested on their allegation that Masimo did have such knowledge, Masimo promptly informed the Arbitrator of the collateral-estoppel consequences of the *Qui Tam* ruling. But the Arbitrator cast aside this Court's

ruling and made findings directly to the contrary. He found that Masimo "knowingly created" intolerable working conditions by pressuring Plaintiffs to sell devices that Masimo "knew" did not meet their FDA-cleared accuracy specification. The Arbitrator even awarded punitive damages, in part, because Masimo tried to rely on this Court's ruling.

The Arbitrator also disregarded the Constitutional limits on punitive damages. Plaintiffs brazenly urged him to do so, arguing his ruling would not be subject to normal appellate review. The Arbitrator obliged by awarding \$5,000,000 in punitive damages, more than 16 times compensatory damages, disregarding the very law he cited. Moreover, the Arbitrator manifestly disregarded Supreme Court precedent when he justified the punitive damages award by relying on potential harm to patients that he thought could result from Masimo's devices. But this alleged potential patient harm is dissimilar to the harm allegedly suffered by Plaintiffs, and thus under that Supreme Court precedent, cannot support the award.

The Arbitrator also denied Masimo a fundamentally fair hearing. He refused to consider evidence proffered by Masimo, applied disparate evidentiary standards to the parties, and failed to rule on Masimo's Cross-Claim. He even justified punitive damages, in part, because Masimo offered to conduct another study under his and the FDA's supervision to confirm the accuracy of its devices.

Furthermore, shortly before the punitive damages hearing, Masimo discovered information that undermined the integrity of the entire Arbitration. Under ethical and procedural obligations acknowledged by the Arbitrator on his disclosure form, he was required to disclose information that would allow the parties to assess his impartiality. Because full disclosure is vital to the integrity of the arbitration process, courts routinely vacate arbitration awards where Arbitrators fail to disclose such information. Despite this strict disclosure

requirement, the Arbitrator never disclosed that his brother is Stephen Neal, a trial lawyer and Chairman of Cooley LLP. Neal was lead counsel representing adversaries of Masimo that lost two highly contentious, high-profile litigations in which Neal's clients have had to pay Masimo over \$600M. Following those victories, Masimo has overtaken Neal's clients as the market leader.

When Masimo first became aware that the Arbitrator is Neal's brother, it immediately challenged the Arbitrator's continued service. The Arbitrator rejected that challenge, unilaterally declaring himself impartial even though JAMS rules require JAMS to decide such challenges. The Arbitrator blamed Masimo for not discovering his relationship to Neal sooner, and subsequently deemed Masimo's challenge to be an "abusive tactic" warranting punitive damages.

Despite the narrowly defined statutory bases for vacating arbitration awards, numerous compelling grounds exist under 9 U.S.C. § 10(a) to vacate the Arbitrator's Final Award. Moreover, because of this Court's ruling in the *Qui Tam* case, this Court should dismiss this action with prejudice.

II. BACKGROUND

A. The Stay Of This Employment Action

Plaintiffs were salesmen who sold Masimo's noninvasive hemoglobin devices known as the Pronto and Pronto-7 (the "Pronto devices"). In May, 2011, Plaintiffs filed this employment action. Dkt. No. 1. They alleged that Masimo wrongfully constructively terminated them in violation of public policy, California Labor Code 1102.5 and the Dodd-Frank Act. *Id.* They also alleged Masimo violated California's Unfair Competition Law. *Id.* Because Plaintiffs and Masimo agreed to arbitrate disputes between them, this Court granted Masimo's Motion to Compel Arbitration and to Stay Proceedings. Dkt. Nos. 10, 28.

B. The Plaintiffs' Qui Tam Case Before This Court

In October 2010, seven months before filing this employment case,

Plaintiffs, along with another former salesperson, filed a *Qui Tam* action against Masimo under the False Claims Act. Ex. 5.¹ Plaintiffs alleged that Masimo defrauded customers and the FDA about the accuracy of the Pronto devices.

Both cases proceeded in parallel. On October 2, 2013, four weeks before trial in the *Qui Tam* case, this Court granted Masimo's Motion for Summary Judgment and dismissed the case. Ex. 4. This Court found that there was no evidence that Masimo had made any false statements, or committed any fraud, about the accuracy of its Pronto devices. *Id.* at 15. This Court's ruling rejected each of Plaintiffs' liability theories and terminated that case. *Id.* at 15-22.

C. The Arbitrator's Awards In The Employment Arbitration

Following this Court's *Qui Tam* ruling, the Arbitrator issued an Interim Award on October 28, 2013, finding Masimo liable for wrongful constructive termination. Ex. 1. On January 16, 2014, the Arbitrator issued his Final Award, including punitive damages. Ex. 2.

The Arbitrator found that the Plaintiffs were compelled to resign because Masimo had "knowingly created and maintained working conditions sufficiently intolerable to cause reasonable employees to resign." *Id.* at 25. But the Arbitrator's award did not rest on how Masimo treated Plaintiffs. Indeed, he found that Masimo treated Plaintiffs well and never retaliated against them. *Id.* at 27-29. Rather, he based liability on his finding that Masimo "knew" its Pronto devices were "faulty and did not perform as claimed." *Id.* at 25.

But this Court in the *Qui Tam* case had already rejected the premise that Masimo knew its devices were inaccurate. *See, e.g.*, Ex. 4 at 15, 17. The Arbitrator disregarded this Court's *Qui Tam* ruling, and awarded Plaintiffs \$310,056 in economic and general damages, and \$5,000,000 in punitive damages. Ex. 2 at 29, 38-39.

¹ All exhibits are to the Declaration of Benjamin J. Everton.

III. THE ARBITRATOR EXCEEDED HIS POWER

The Federal Arbitration Act ("FAA") sets forth several bases for vacating an arbitration award, including "where the arbitrators exceeded their powers." 9 U.S.C. § 10(a)(4). An arbitrator exceeds his powers "when the award is 'completely irrational,'" such that it fails "to draw its essence from the agreement." *See Comedy Club, Inc. v. Improv W. Assocs.*, 553 F.3d 1277, 1288 (9th Cir. 2009).

A. The Arbitrator Exceeded His Power Under The Agreement

The Arbitrator's Award went well beyond the parties' agreement to arbitrate "disputes between the Employee and the Company." Ex. 3 at ¶ 1. The Arbitrator's ruling of constructive termination, his sole liability ruling, was that Plaintiffs were compelled to quit because he found Masimo's Pronto devices were "faulty and did not perform as claimed." Ex. 2 at 25; *see also id.* at 25-28 (finding the devices "inaccurate and unreliable," "not ready for market," "defective," and had a "false" accuracy specification).

Because Masimo was the first company to invent devices that measured hemoglobin noninvasively (SpHb), no specific standard existed to validate such devices. However, a standard known as "ISO 9919" provided accuracy validation guidelines for the underlying pulse oximeter technology (SpO2). The FDA and Masimo discussed this and agreed that Masimo would validate its SpHb accuracy according to this ISO standard. Ex. 6 at 2 ("ISO 9919:2005 is the applicable standard for the Masimo SpHb devices."); Ex. 31 at 1883-84. ISO 9919 provides that "measurements from patients in [a clinical] environment can be degraded because data collection cannot always be well controlled. SpO2 measurements are better controlled under laboratory conditions." Ex. 7 at 57. It expressly recognizes that data collected in clinical environments from the pulse oximeter equipment and from the laboratory device are "difficult to match reliably, due to circulatory instabilities or dynamics." *Id.* Thus, ISO 9919

directs testing "under well-controlled, optimal laboratory conditions on healthy adult subjects." *Id.* at 52.²

In accordance with ISO 9919, Masimo validated its accuracy specification in controlled laboratory conditions. Ex. 8. Though not required by ISO 9919, Masimo went further, and also validated its accuracy in numerous clinical sites. Exs. 8, 9. Every ISO 9919 validation study confirmed Masimo's accuracy specification. *Id.* The FDA relied on three of the validation studies to clear Masimo's accuracy specification four times. Ex. 9.

However, the Arbitrator substituted his own judgment for that of the ISO and decided Masimo was wrong to have relied on the controlled ISO 9919 testing in determining the accuracy specification. Ex. 2 at 33. The Arbitrator even justified punitive damages in part because Masimo relied on controlled laboratory testing. *Id.* Instead, based on his own view of "common sense," the Arbitrator found *sua sponte* that "*the critical test* of any device intended to be used with real patients in the real world is real world performance, *not laboratory performance*." *Id.* (emphasis added). The Arbitrator made this finding even though no one suggested this methodology, and even though the ISO methods Masimo followed explain why testing in a controlled setting is how to determine clinical performance.³ Ex. 7 at 52, 57.

The Arbitrator's finding that Masimo was wrong to use controlled testing led to his conclusion that Masimo's devices were "faulty and did not perform as

² Controlled testing is used because, as recognized by this Court and by ISO, numerous known confounders obscure the accuracy in clinical settings. Ex. 4 at 7; *see also* Ex. 31 at 1885-88, 1933-34; Ex. 42 at 15-16; Ex. 43 at 41-43, 56-57; Ex. 44; Ex. 47. FDA regulations expressly endorse "well-controlled investigations" to validate medical devices and reject uncontrolled data. *See* 21 C.F.R. §860.7(c)(1)-(2).

³ This finding also directly conflicted with the only FDA expert to testify at the Arbitration. Ex. 31 at 1857-59, 1885-86.

claimed." Ex. 2 at 25. This conclusion was the centerpiece of his wrongful constructive termination and punitive damages rulings. *Id.* at 25-27, 30-33. However, the parties never agreed to arbitrate whether Masimo was correct to follow ISO-9919. Moreover, the task of an arbitrator is not to make public policy. *Stolt-Nielsen S. A. v. AnimalFeeds Int'l Corp.*, 559 U.S. 662, 671-72 (2010) (vacating award where arbitrator exceeded powers under § 10(a)(4)). Because the Arbitrator "imposed [his] own view of sound policy" on what constitutes proper testing of Masimo's medical devices, he exceeded his power. *Id.* Thus, the Award does not draw "from the essence of the agreement." *Comedy Club*, 553 F.3d at 1288. Accordingly, this Court should vacate the award under 9 U.S.C. § 10(a)(4).

B. The Arbitrator Was Also Preempted From Deciding Proper Testing For Masimo's Devices

The Arbitrator also exceeded his power because he was preempted from deciding the proper testing methodology for determining the accuracy specification for the Pronto devices. Masimo presented the preemption law to the Arbitrator, and he correctly acknowledged that he was preempted from deciding issues involving alleged fraud on the FDA, or issues that "threaten to interfere with FDA processes." Ex. 2 at 23-24, 27, 29. However, the Arbitrator disregarded that same law in declaring his own "critical test" to conclude that Masimo was liable because its devices did not meet their FDA-cleared accuracy specification that was determined using ISO 9919 methodology. *Id.* at 33.

The Food Drug and Cosmetic Act (FDCA) bars private enforcement of that statute. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (citing 21 U.S.C. § 337(a)) (holding state-law claim for fraud on the FDA impliedly preempted by FDCA); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323-24 (2008) (holding various state-law claims expressly preempted by FDCA). The Ninth Circuit has applied these Supreme Court cases to hold

that a claim that defendants misled patients by failing to disclose that an eye laser was not FDA-approved for their surgeries was both expressly and impliedly preempted. *Perez v. Nidek Co.*, 711 F.3d 1109, 1119-20 (9th Cir. 2013). In *Perez*, the Ninth Circuit found the claim expressly preempted because it was dependent on a requirement that was "different from, or in addition to" the requirements under the FDCA. *Id.* at 1118. Additionally, in finding the claim impliedly preempted, the Ninth Circuit held that the state-law claim necessarily encroached on the FDA's regulatory authority. It held:

Whether Defendants' use of the laser was in violation of the FDCA depends on, among other things, the scope of the [Premarket Approvals], whether the Lasers were modified so that they were "adulterated" under section 501(f)(1)(B) of the FDCA, whether Defendants were engaged in a permissible "off label" use of the Laser, and whether re-certification of the device was required under 21 C.F.R. § 1040.10. All of these matters rest within the enforcement authority of the FDA, not this Court.

Id. at 1120.⁴

Here, Plaintiffs alleged that the Pronto devices failed to meet the FDAcleared accuracy specification in violation of the FDCA and FDA regulations.

⁴ Courts even bar other federal claims in view of the FDCA. For example, the Ninth Circuit held that the FDCA barred a claim under the Lanham Act. *PhotoMedex v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010). The plaintiff in *PhotoMedex* accused a manufacturer of selling a skin laser without 510(k) clearance. *Id.* at 926. Upon learning of the allegations, the FDA responded by conducting an on-site inspection of the manufacturer. *Id.* at 926-27. After the inspection, the manufacturer filed a 510(k) application, which was approved. *Id.* The Ninth Circuit held that the plaintiff was "not permitted to circumvent the FDA's exclusive enforcement authority by seeking to prove that Defendants violated the FDCA, when the FDA did not reach that conclusion." *Id.* at 928; *see also POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1176 (9th Cir. 2012) (FDCA bars false-labeling claim), *cert. granted*, 134 S. Ct. 895 (2014).

Exhibit 10 at 94; Ex. 11. The Arbitrator found that the Pronto devices were "faulty and did not perform as claimed" according to their FDA accuracy specification. Ex. 2 at 25, 27. As explained above, this finding is based on the Arbitrator's new "critical test," rather than the ISO 9919 testing. *Id.* at 33. But the FDA and Masimo had agreed on ISO 9919 as the testing methodology to define the specification. Ex. 6 at 2. The Arbitrator also found Masimo was liable for requiring Plaintiffs to sell devices according to their FDA-cleared specification. Ex. 2 at 25, 27. But FDA regulations require Masimo to market the devices in that way. Ex. 31 at 1885-86; Ex. 4 at 19. Thus, both of the Arbitrator's key predicate findings are preempted.

The Arbitrator claimed he was not preempted because he determined his findings do "not threaten to interfere with FDA processes." Ex. 2 at 27. But using his "critical test," rather than controlled testing under ISO 9919, *does* interfere with the FDA process. The FDA and Masimo discussed how Masimo should determine accuracy under ISO 9919, and the FDA did not require more. Ex. 6. Thus, the Arbitrator's "critical test" contradicts his statement that the "FDA, not arbitrators, has the power to determine what should be submitted to it, and to order accordingly." Ex. 2 at 29.

The Arbitrator also claimed that his findings were not preempted because they did not "involve[] a state imposing a requirement on a medical device that is inconsistent with requirements imposed by the FDA." *Id.* at 27. However, the Arbitrator's ruling that Masimo should not have promoted its devices according to their FDA-cleared specifications *does* impose requirements that contradict those imposed by the FDA. *Id.* at 27, 33; Ex. 31 at 1885-86; Ex. 4 at 19.

Finally, the Arbitrator's Interim Award found that Plaintiffs had shown fraud. Ex. 2 at 2, 30, 32. While the Arbitrator never identified the alleged fraud, he did find "that [Masimo] flouted [] directives from the FDA" when seeking clearance on the Pronto-7. *Id.* at 12. He also found Masimo "knew" its

accuracy specifications were false. *Id.* at 27, 32. But the Arbitrator acknowledged he was preempted from deciding issues of fraud on the FDA. Ex. 2 at 24. By deciding preempted issues, the Arbitrator again exceeded his power, and this Court should vacate his ruling under 9 U.S.C. § 10(a)(4).

IV. THE ARBITRATOR MANIFESTLY DISREGARDED THE LAW

The Ninth Circuit also authorizes vacatur under 9 U.S.C. § 10(a)(4) of an arbitration award that exhibits a "manifest disregard of law." *Kyocera Corp. v. Prudential-Bache T Servs.*, 341 F.3d 987, 997 (9th Cir. 2003) (internal citations omitted); *Comedy Club*, 553 F.3d at 1290. An arbitrator's award is in manifest disregard of the law where it is "clear from the record that the arbitrator[] *recognized* the applicable law and then *ignored* it." *Id.* (emphasis added) (citing *Michigan Mut. Ins. Co. v. Unigard Sec. Ins. Co.*, 44 F.3d 826, 832 (9th Cir. 1995)). Here, the Arbitrator's refusal to give any effect to this Court's October 2, 2013 summary judgment ruling in the *Qui Tam* case warrants vacatur and dismissal. Ex. 2 at 20-22.

A. The Arbitrator Manifestly Disregarded The Collateral Estoppel Effect Of This Court's Rulings In The Qui Tam Case

In addition to deciding federal regulatory issues beyond his authority, the Arbitrator rejected contrary findings from the judicial entity having authority to review such issues – this Court. The Arbitrator based his liability Award on findings that directly contradict this Court's prior *Qui Tam* ruling.

1. The Arbitrator Recognized But Ignored The Correct Standard For Collateral Estoppel

After this Court issued its summary judgment ruling in the *Qui Tam* case, the Arbitrator correctly recognized several important points concerning collateral estoppel: 1) that "certain determinations in the summary judgment order appeared to overlap with issues in the arbitration;" 2) that collateral estoppel bars a party from "re-litigating an issue determined against that party in

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an earlier action;" 3) that the "requirements of the doctrine are that the issue or issues subject to the estoppel must be identical to those in the prior actions, and that the issues were fully and fairly litigated in the prior action;" and 4) that one of the goals of collateral estoppel is to "avoid unseemly inconsistent judgments." Ex. 2 at 20. The Arbitrator also was made aware that he was bound by prior federal court decisions. See Ex. 12 (Opening Br.) at 1 (citing Aircraft Braking Sys. Corp. v. Local 856, 97 F.3d 155, 159 (6th Cir. 1996)); see also Collins v. D.R. Horton, Inc., 505 F.3d 874, 880 (9th Cir. 2007).

However, the Arbitrator disregarded the collateral estoppel law and refused to give effect to this Court's ruling because the *claims* in the two cases were different. See, e.g., Ex. 2 at 21. ("The gravamen of [Plaintiffs'] claims in the arbitration is distinctly different [than in the Qui Tam case]."). The Arbitrator pointed out Masimo's immaterial acknowledgment in the Qui Tam case that "the arbitration *claims* and the *qui tam claims* are not the same." *Id.* (emphasis added). The Arbitrator also concluded that there was no "full and fair hearing in the District Court of the *claims* presented in the arbitration." *Id.* at 22 (emphasis added). But there was no dispute that the claims in the two matters are different. The relevant question is the identity of issues.

The Arbitrator's focus on the *claims*, rather than on the underlying *issues*, manifestly disregarded the collateral estoppel law he properly outlined. It also side-stepped the Plaintiffs' repeated unequivocal admissions about the legally pertinent question – whether there were underlying *issues* in the *Qui Tam* case that were the same as those in the Arbitration. Indeed, the Arbitrator knew that Plaintiffs admitted the following:

- "[T]he Arbitration and this qui tam action involve a 'substantial identity of issues." Ex. 13 at 4 (emphasis added).
- "The underlying issues in the Dodd-Frank Arbitration and this qui tam suit are *one and the same*." *Id*. (emphasis added).

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- "[T]he *issues* that caused [Plaintiffs'] resignation are the *same issues* that gave rise to this *qui tam* action." *Id.* at 5 (emphasis added).
- "Although the arbitration involved employment matters, that preceding [sic] involved the *same issues* as presented here." Ex. 14 at 12 (emphasis added).
- "Indeed, the claims here were the *underpinning* of the claims and defenses in that case. Mr. Ruhe and Mr. Catala's decision to quit Masimo was because of everything they allege now as FCA violations." *Id.* (emphasis added).
- "Defendant's violations of the FCA were the *basis* for quitting." *Id*. (emphasis added).

See Ex. 12 (Opening Br.) at 2, 7. The Arbitrator also knew that Plaintiffs had argued to this Court that the identity of underlying *issues* between the two cases would mandate that *any* eventual Arbitration ruling would collaterally estop *this Court*. *Id.* at 2 (citing Ex. 13 at 10). But the Arbitrator simply ignored his proper recitation of the correct question of identity of *issues*, relying instead on the irrelevant difference in *claims*. He then even justified punitive damages against Masimo for relying on this Court's ruling because Masimo had argued the difference in the claims in the *Qui Tam* case. Ex. 2 at 20-22, 34.

2. <u>Collateral Estoppel Applies</u>

This Court's summary judgment ruling and the Arbitrator's Award decided the same underlying issues, though with completely opposite conclusions. For example, this Court rejected the underlying premise that Masimo promoted devices that it knew did not meet their FDA-cleared specification, or committed fraud. Ex. 4 at 15-20. This Court held that "[Plaintiffs'] evidence is simply not sufficient to raise a triable dispute that Masimo knowingly made false statements about the accuracy of the Pronto Devices." *Id.* at 20; *see also id.* ("Even if [Plaintiffs] could establish that the

Pronto Devices are inaccurate to a material degree, they have presented no evidence that Masimo did not have a good faith belief that its devices were accurate."). The Court also held that "[Plaintiffs'] evidence fails to demonstrate any false statement or fraudulent conduct by Masimo" *Id.* at 15; *see also id.* at 16-20.

The Arbitrator rejected this Court's rulings and found that Masimo "knowingly created and maintained" an intolerable working condition by pressuring Plaintiffs to sell devices that Masimo knew did not meet their accuracy specification. Ex. 2 at 25. His Interim Award even found that Masimo committed fraud, warranting punitive damages. Ex. 1 at 44. The Arbitrator also found that Masimo was wrong to sell the devices according to their FDA-cleared specification, despite this Court's finding that Masimo was required to market its devices consistent with that specification. Ex. 2 at 25, 27; Ex. 4 at 19.

In rejecting this Court's rulings, the Arbitrator stated that this Court only "briefly addressed the question of device inaccuracy, [which was] central in the arbitration," and that this Court's "discussion [about accuracy] is limited to about two pages, near the end of its ruling" Ex 2 at 22. However, that portion of this Court's opinion is entitled "Accuracy of the Pronto Devices." Ex. 4 at 18-20. It explicitly contradicts the Arbitrator's central finding that Masimo knew its devices did not meet their accuracy specification, and that Masimo committed fraud. *Compare id. with* Ex. 2 at 25, 30, 32-33.

The Arbitrator also rejected this Court's rulings because this Court supposedly did not consider evidence relating to device withdrawals, the departure of other Masimo sales personnel, "extensive" evidence of device inaccuracy and disparaging comments. Ex. 2 at 22. However, this Court's Opinion directly refutes the Arbitrator's claim. *See, e.g.*, Ex. 4 at 18 ("Relators submitted evidence of customer feedback on device accuracy and internal discussions with Masimo about improving the accuracy of the devices.").

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Moreover, the Arbitrator was aware that Plaintiffs had argued to this Court that the same evidence was presented in both cases:

[Masimo's] violations of the FCA were the basis for quitting. Hence, nearly all the *same documents, testimony, and other evidence* has been exchanged between the parties and relied in both cases. Indeed, the arbitration closing and summary judgment briefing discuss *many of the same points* including the product's lack of accuracy, failure to meet performance standards, and improper marketing.

Ex. 12 (Opening Br.) at 2 (citing Ex. 14 at 12-13) (emphasis added). In the summary judgment hearing before this Court, Plaintiffs reiterated their argument that the Arbitrator had considered all the same evidence before this Court on summary judgment. Ex. 38 at 45-46. Indeed, Plaintiffs submitted to this Court more than 230 Arbitration exhibits, 1600 pages of the Arbitration transcript, 10 different Arbitration depositions, and several expert declarations. Everton Decl. ¶¶ 39-40. That evidence bore directly on the topics above alleged by the Arbitrator to not have been before this Court. *Id.*; Ex. 2 at 22. Thus, nothing shows that this Court did not fully and fairly consider all the relevant evidence.

Accordingly, the Arbitrator acknowledged but manifestly disregarded the law on collateral estoppel by refusing to give any effect to this Court's prior rulings. Thus, this Court should vacate the Award. *See, e.g., Aircraft Braking Sys. Corp.*, 97 F.3d at 159, 161-62 (affirming vacatur for failure to apply collateral estoppel); *John Morrell & Co. v. Local Union 304A*, 913 F.2d 544, 562-64 (8th Cir. 1990) (same); *Telephone Workers Union of New Jersey et al. v. New Jersey Bell Tel. Co.*, 584 F.2d 31, 32-33 (3d Cir.1978) (refusing to confirm an arbitration award that was contrary to prior judicial decree); *Ransom & Randolph Co. v. Local 12, Int'l Union*, 3:06-CV-2710, 2007 WL 2626187, at *1

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n.1 (N.D. Ohio Sept. 6, 2007). In addition, because this Court has already rejected the underlying issues upon which Plaintiffs based their wrongful constructive termination claim, this Court should dismiss this action as barred under the doctrine of collateral estoppel.

3. The Arbitrator's Award Frustrates The Policy of Avoiding Unseemly Inconsistent Judgments

The Arbitrator acknowledged that one of the policy goals of collateral estoppel is to "avoid unseemly inconsistent judgments." Ex. 2 at 20. The Arbitrator disregarded that policy by issuing an Award wholly inconsistent with this Court's prior determination that Masimo did not knowingly promote inaccurate devices. Plaintiffs then exacerbated the inconsistency. After this Court calendared this Motion, Plaintiffs' counsel, also lead counsel of record in the Qui Tam case, issued a press release touting the Arbitrator's Award as if it were the final word on whether Masimo's devices met their FDA specification and whether Masimo had knowledge they did not. Ex. 29. Lead counsel's release, as does the Final Award, contradicts numerous findings by this Court that there was no evidence Masimo knowingly made any false statements or misled anyone about the accuracy of its devices. Ex. 4 at 2, 15-20. A published news report has also pointed out that the Arbitrator "ruled the exact opposite" of this Court. Ex. 30 at 2. This public discourse about unseemly inconsistent rulings, fueled by Plaintiffs' counsel, intensifies public dissatisfaction with the judicial process – a natural consequence when the doctrine of collateral estoppel is cast aside, as the Arbitrator did here. *Id.* at 1-3.⁵

⁵ The Arbitrator also justified his refusal to apply collateral estoppel because, by the time of this Court's rulings, he had assembled "a substantial draft award [that was] near completion." Ex. 2 at 22. He concluded that applying collateral estoppel would not achieve the policy of preventing duplicative litigation. *Id.* But Plaintiffs filed the *Qui Tam* case first, and it was decided first. The failure to gain one benefit of collateral estoppel simply

4. The Arbitrator Punished Masimo For Arguing Estoppel

Finally, the Arbitrator rationalized punitive damages against Masimo for trying "to impose the District Court's ruling in the arbitration." Ex. 2 at 34. The Arbitrator chastised Masimo for having argued to this Court that the claims in the two cases are different, and even faulted Masimo for the parallel proceedings. *Id.* But, Masimo based its collateral estoppel argument on the underlying *issues*, exactly as the Plaintiffs did when arguing to this Court that it would be collaterally estopped by the Arbitrator's ruling if it issued first. Ex. 13 at 10-11. By justifying punitive damages based on Masimo's assertion of collateral estoppel, the Arbitrator confirmed his manifest disregard of the law.

B. The Arbitrator Manifestly Disregarded The Law Governing Punitive Damages

1. The Arbitrator Wrongly Relied On Third-Party Harm

In the Interim Award, the Arbitrator held Claimants were entitled to punitive damages in part because Masimo allegedly knew of potential harm to third-party patients. Ex. 1 at 44. In the Final Award, he carried forward that holding and, in assessing the amount of the punitive damages, held that the alleged potential harm to those third parties was "a critical point on perhaps the *most* critical issue re the amount of punitive damages" Ex. 2 at 30, 34 (emphasis original).

Masimo argued that the alleged potential harm to third-party patients was dissimilar to the alleged harm to the Plaintiffs. Ex. 15 at 15-21. Indeed, Plaintiffs never even suggested that Masimo's devices somehow harmed them. Masimo explained the relevancy of this argument in view of two Supreme Court decisions, *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003),

because of how Plaintiffs happened to file their separate cases does not trump the controlling legal elements of collateral estoppel – especially when the policy goal of avoiding inconsistent judgments is also achieved by applying estoppel.

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and Philip Morris USA v. Williams, 549 U.S. 346 (2007). See Ex. 15 at 18-21.

In *State Farm*, the conduct that harmed third parties was dissimilar to the conduct that harmed plaintiffs. The Court held: "Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis" *See* 538 U.S. at 423. The Court applied that rule and held: "[B]ecause [Plaintiffs] have shown no conduct by State Farm similar to that which harmed them, the conduct that harmed them is the only conduct relevant to the reprehensibility analysis." *Id.* at 424.

In *Philip Morris*, a tobacco case, the conduct that harmed third parties was similar to the conduct that harmed plaintiff. 549 U.S. at 350-51. Supreme Court observed that this conduct was available show reprehensibility because it "also posed a substantial risk of harm to the general public." Id. at 355. But the Court elaborated on State Farm, explaining: "We have said that it may be appropriate to consider the reasonableness of a punitive damages award in light of the potential harm the defendant's conduct could have caused. But we have made clear that the potential harm at issue was harm potentially caused *the plaintiff*." *Id.* at 354 (citing *State Farm*, 538 U.S. at 424) (emphasis in original).

Thus, *Philip Morris* and *State Farm* indicate that third-party harm can be considered in the reprehensibility analysis only when the conduct at issue gives rise to the same harm to both the plaintiff and the third party.

Despite the Arbitrator's awareness of both *Philip Morris* and *State Farm*, he expressly relied on the dissimilar alleged potential harm to third-party patients in finding reprehensibility to justify exorbitant punitive damages. Ex. 2 at 30-39. Indeed, he found that the alleged potential harm to third parties was "a critical point on perhaps the *most* critical issue re the amount of punitive damages" *Id.* at 34. The Arbitrator's recognition of, but refusal to follow,

State Farm and Philip Morris was a manifest disregard of the law.

2. The Arbitrator Ignored Constitutional Limits

The Arbitrator also recognized, but then refused to follow, established Constitutional limits on the amount of punitive damages. The Arbitrator recognized that punitive damages exceeding a single-digit ratio between the compensatory and punitive award is presumptively unconstitutional. Ex. 2 at 35-36; see also State Farm, 538 U.S. at 425 ("[F]ew awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process."). Plaintiffs brazenly urged the Arbitrator to ignore the Constitutional limits because his ruling would not be subject to traditional appellate review. Ex. 16 at 1-3; Ex. 2 at 35. While the Arbitrator claimed to reject that argument, he awarded presumptively unconstitutional punitive damages, here 16 times the compensatory damages. Ex. 2 at 34-39.

The Arbitrator rationalized his decision to award \$5 million in punitive damages based on alleged potential harm to patients, his unsupported view that \$310,000 is a small compensatory award, and supposed litigation abuse by Masimo. *Id.* at 34-38. The Arbitrator's table of cases exposes that he disregarded the very cases he cites. Specifically, with the exception of the *Bullock* tobacco case, the only case with a comparable compensatory damage award applied a 1:1 ratio. Ex. 2 at 36 (*see*, *e.g.*, *Casella*, with \$240,000 in compensatory damages and a 1:1 ratio).⁶ And, each of the listed wrongful termination cases applied a ratio of 1:1 or less (*Belk, Casella, Czarnik, Green, Halloran, and Roby*). *Id.* The Arbitrator's table also reveals that for the non-

⁶ The tobacco cases appear to constitute a special category of cases in view of the enormous number of deaths and serious health problems that tobacco causes. The Arbitrator irrationally analogized tobacco cases to the present case to justify awarding punitive damages 16 times compensatory damages even though there was no evidence that any patient was ever harmed by a Masimo device. *See* Ex. 2 at 38.

wrongful-termination cases listed, only those with a compensatory award under \$60,000 had a ratio that exceeded the presumptive single-digit constitutional limit. *Id.* (*e.g.*, *Deters*, *EEOC*, *Hampton*, *Romano*, *Swinton*). The Arbitrator manifestly disregarded the law he cites in awarding punitive damages 16 times compensatory damages. This warrants vacatur of his punitive damages award.

V. THE ARBITRATOR WAS GUILTY OF MISCONDUCT BY DENYING MASIMO A FUNDAMENTALLY FAIR HEARING

Courts are authorized under 9 U.S.C. § 10(a)(3) to vacate an arbitrator's award where the arbitrator is "guilty of misconduct . . . in refusing to hear evidence pertinent and material to the controversy; or of any other misbehavior by which the rights of any party have been prejudiced." Vacatur is appropriate when an arbitrator's misconduct constitutes a denial of fundamental fairness in the arbitration proceeding. *See In Matter of Watkins-Johnson Co. v. Pub. Utilities Auditors*, C-95 20715 RMW(E.I.), 1996 WL 83883, at *2 (N.D. Cal. Feb. 20, 1996) (vacating award under predecessor to Section 10(a)(3)). Here, the Arbitrator refused to consider evidence and applied inconsistent standards to the parties, denying Masimo a fundamentally fair hearing.

For example, the Arbitrator criticized Masimo for relying on the FDA's 2011 inspection report because Masimo "did not call the authors to testify and explain the report." Ex. 2 at 16, 23. In contrast, the Arbitrator relied on Plaintiffs' presentation of FDA correspondence to find that Masimo "flouted" the FDA without requiring the Plaintiffs to "call the authors to testify and explain" it. *Id.* at 11-12. This was particularly egregious because the Arbitrator acknowledged that he may not have understood that same correspondence. *Id.*

As another example, the Arbitrator claimed that Masimo was "unrepentant" at the Arbitration hearing and awarded punitive damages because "the senior executives continued to assert that the devices always conformed to

specification" Ex. 2 at 30.⁷ However, the hearing took place in 2013. *Id.* at 1. By that time, Masimo's executives had learned a great deal more about the product than they knew in 2009 and 2010. By 2013, Masimo's devices had been confirmed accurate by over 20 validation studies conducted according to ISO 9919. Ex. 8. Thus, this 2013 testimony endorsing accuracy did not reflect defiance, but justified confidence in years of methodical scientific studies. But the Arbitrator refused to consider this evidence. Ex. 2 at 31-32; Ex. 17 at 6. Because the Arbitrator supported punitive damages with his view of this *2013* testimony, his refusal to admit the validation evidence that formed the basis of this testimony prejudiced Masimo and denied it a fundamentally fair hearing. Ex. 2 at 30, 33-34.

The Arbitrator also denied Masimo a fundamentally fair hearing on punitive damages. In December 2011, the Arbitrator bifurcated the liability and punitive damages phases of the case. Ex. 39 at 4. This conveyed that the parties would submit evidence in two phases. After the Interim Award, the Arbitrator confirmed he would accept evidence regarding punitive damages. Ex. 40.

To refute any suggestion that Masimo's behavior was reprehensible, Masimo offered to conduct another study, under his and the FDA's supervision, to confirm its devices' accuracy. Ex. 17 at 1-2. However, the Arbitrator rejected Masimo's offer for a new study, and even found that the mere offer was an "abusive tactic" justifying punitive damages. *Id.* at 6; Ex. 2 at 33-34.

The Arbitrator's failure to consider pertinent evidence and to provide Masimo with a fundamentally fair hearing is also evident in his failure even to rule on Masimo's Cross-Claim. Months before Plaintiffs quit, they contacted a lawyer and then stole thousands of confidential Masimo documents. Ex. 18.

⁷ While accusing Masimo of being unrepentant, the Arbitrator ignored evidence showing that it was actually Plaintiffs who were callous towards patient safety. *See*, *e.g.*, Ex. 41 at 12, 13.

Masimo brought a Cross-Claim for conversion and breach of contract, which the parties briefed. Ex. 19. Although the Arbitrator acknowledged Masimo's Cross-Claim in his Award, he made no ruling on it. Ex. 2 at 17, 19.

The Arbitrator's failure to provide Masimo with a fundamentally fair hearing substantially prejudiced Masimo, warranting vacatur of his Award under 9 U.S.C. § 10(a)(3).

VI. THE ARBITRATOR DEMONSTRATED EVIDENT PARTIALITY

Finally, the FAA authorizes vacating an arbitration award under 9 U.S.C. 10(a)(2) for "evident partiality." Vacatur on this basis merely requires an arbitrator's failure to disclose facts suggesting partiality, not actual bias. *See Commonwealth Coatings Corp. v. Cont'l Cas. Co.*, 393 U.S. 145, 147, 149 (1968). "[T]he legal standard for evident partiality is whether there are facts showing a reasonable impression of partiality." *New Regency Prods., Inc. v. Nippon Herald Films, Inc.*, 501 F.3d 1101, 1106 (9th Cir. 2007) (quoting *Schmitz v. Zilveti*, 20 F.3d 1043, 1048 (9th Cir. 1994)) (internal quotations omitted). "In a nondisclosure case, the integrity of the process by which arbitrators are chosen is at issue." *Schmitz*, 20 F.3d at 1047. Thus, "[s]howing a 'reasonable impression of partiality' is sufficient in a nondisclosure case because the policy of section 10(a)(2) instructs that the parties should choose their arbitrators intelligently." *Id.*

A. The Arbitrator Failed To Disclose The Identity Of His Brother, Who Is A Long-Time Masimo Adversary

Before his appointment, the Arbitrator provided the parties with his disclosure form under CCP § 1281.9, JAMS Ethical Guidelines and the CRC Ethics Standards, disclosing information to allow the parties to assess his impartiality. Ex. 21; *see also* Exs. 20, 28, 48. Based on those authorities, Question 13 in his disclosure form required him to identify any matter that "[m]ight cause a person aware of the facts to reasonably entertain a doubt that

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the arbitrator would be able to be impartial." Ex. 21 at 4; see Mt. Holyoke Homes, L.P. v. Jeffer Mangels Butler & Mitchell, LLP, 219 Cal. App. 4th 1299, 1310-12 (2013) (vacating under CCP § 1281.9 and Ethics Standards).

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Never did the Arbitrator disclose that his brother is Stephen Neal, a litigator and also Chairman of the large law firm Cooley LLP. Ex. 21; Ex. 22. The identity of the Arbitrator's brother would certainly cause a reasonable person in Masimo's position to reasonably entertain a doubt that the Arbitrator would be able to be impartial. Stephen Neal and the firm he chairs are longtime Masimo adversaries, and both have suffered huge, high-profile litigation losses to Masimo. Ex. 24. These losses include an antitrust case in which Stephen Neal was lead trial counsel for Tyco Healthcare Group LLP. *Id.* at 1-10, 26-32; Ex. 25. There the jury returned a verdict against Tyco that was the fifth-largest jury award of 2005, and the third largest in California. *Id.* at 28-37. A year earlier, Stephen Neal and his firm represented Tyco's wholly owned subsidiary, Nellcor Puritan Bennett Inc., in a case where his firm lost to Masimo in one of the largest medical device patent verdicts of the time. Ex. 49; Ex. 24 at 2, 6, 10, 19, 21, 26-27, 38. Both trials lasted over a month in Los Angeles, where the Arbitrator works. Ex. 24 at 2, 6, 21, 25-27. The cases were reported in local and national newspapers. *Id.* at 1-19, 28-30, 38-40.

Nellcor also had to stop selling its infringing products, settled the matter by paying hundreds of millions of dollars to Masimo, and lost significant market share to Masimo. Ex. 24 at 21, 25, 55. Stephen Neal's firm remains adverse to Masimo in litigation matters to this day. Ex. 26.

That the Arbitrator's brother is a litigator actively practicing in this District is information a party reasonably would want to know in selecting an arbitrator. Given Stephen Neal's well-publicized losses to Masimo, certainly, a reasonable person aware of the facts might reasonably entertain a doubt that the Arbitrator would be able to be impartial. Holyoke, 219 Cal. App. 4th at 131011, 1314 (vacating award for failure to disclose under CCP requirements). This information also creates a reasonable impression of partiality. *New Regency*, 501 F.3d at 1105, 1111 (vacating award for failure to disclose under FAA requirements). Accordingly, the Arbitrator should have disclosed at least the identity of his brother practicing in this district. *See*, *e.g.*, Rothenberg Decl. ¶¶ 9, 14, 17, 19. By so doing, he would have given the parties the knowledge necessary to evaluate his impartiality. *Id*.

The Supreme Court has admonished the courts to be "more scrupulous to safeguard the impartiality of arbitrators than judges, since the former have completely free rein to decide the law as well as the facts and are not subject to appellate review." *Commonwealth*, 393 U.S. at 149. Thus, the role of determining an arbitrator's impartiality "is best consigned to the parties, who are the architects of their own arbitration process, and are far better informed of the prevailing ethical standards and reputations within their business." *Id.* at 151; *see also Schmitz*, 20 F.3d at 1047.

Here, the Arbitrator denied Masimo the opportunity to even consider whether it wanted to put its fate in the hands of the brother of its long-time adversary. Instead, the Arbitrator withheld this information and subsequently issued an exorbitant punitive damages award against Masimo that the Arbitrator admitted was unlike "any of the other hundreds of awards he has rendered over the past dozen years." Ex. 2 at 39.

Under either the FAA or CCP disclosure requirements, Masimo need not show that this was the result of any actual bias. *See, e.g., Holyoke*, 219 Cal. App. 4th at 1311; *New Regency*, 501 F.3d at 1105. Rather, because the Arbitrator failed to disclose his brother, both 9 U.S.C. § 10(a)(2) and CCP § 1286.2(a)(6) require vacatur of his Final Award. *See, e.g., Holyoke*, 219 Cal.

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App. 4th at 1311; New Regency, 501 F.3d at 1111.8

В. The Arbitrator Exceeded His Power By Deciding Masimo's **Challenge**

As soon as Masimo learned about the Arbitrator's brother, it immediately notified JAMS and the Arbitrator, and challenged the Arbitrator's continued service. Ex. 22. But the Arbitrator himself dismissed the challenge, ignoring JAMS Rule 15(i) which requires JAMS, and not the Arbitrator, to decide Masimo's challenge. Ex. 23; Ex. 27 at 17. In deciding this issue himself, the Arbitrator once again exceeded his power in the Arbitration.

VII. <u>CONCLUSION</u>

Based on the foregoing, Masimo respectfully requests the Court vacate the Arbitrator's Final Award. In addition, the Court should dismiss this action with prejudice as barred under the doctrine of collateral estoppel.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 3, 2014 By: /s/ Joseph R. Re

> Joseph R. Re Stephen C. Jensen Joseph S. Cianfrani Payson J. LeMeilleur

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⁸ For additional cases vacating arbitration awards under either the FAA or CCP for an arbitrator's failure to disclose, see Commonwealth, 393 U.S. at 147; Schmitz, 20 F.3d at 1049; HSMV Corp. v. ADI Ltd., 72 F. Supp. 2d 1122, 1132 (C.D. Cal. 1999); Gray v. Chiu, 212 Cal. App. 4th 1355, 1366 (2013); Vitale v. Morgan Stanley Smith Barney, LLC, No. 37-2012-99813, 2012 WL 40773833 (Cal. Super. Ct. Sept. 17, 2012) (Ex. 46); Advantage Med. Servs., LLC v. Hoffman, 160 Cal. App. 4th 806, 809 (2008); Int'l Alliance of Theatrical Stage Employees v. Laughon, 118 Cal. App. 4th 1380, 1382-83 (2004).